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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,150	10/19/2001	Gabriele Nelles	450117-03515	7815
20999	7590	11/12/2003	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER

1651

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,150	NELLES ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2/27/02</u> . | 6) <input type="checkbox"/> Other: _____ |

The preliminary amendment of 10/19/01 canceled claims 39 and 40, and amended claims 3, 4, 6, 8, 12, 17-20, 22, 24, 25 and 28-38.

Claims examined on the merits are 1-38 which are all claims in the application.

Specification

The disclosure is objected to because of the following informalities: the specification fails to contain headings designating different sections.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).

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- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A
"Sequence Listing" is required on paper if the application
discloses a nucleotide or amino acid sequence as defined in
37 CFR 1.821(a) and if the required "Sequence Listing" is
not submitted as an electronic document on compact disc).

The following amendments to the specification are suggested:

Page 1, above the first paragraph insert ---

Background of the Invention ---.

Page 2, above the first full paragraph insert ---

Summary of the Invention ---.

Page 2, below the first full paragraph insert ---

Brief Description of the Drawings

(insert a brief description of each drawing)

Detailed Description of the Invention ---.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to enable using both cell-growth promoting molecules and cell-growth inhibiting molecules together as encompassed by reciting "and/or" in line 2 of claim 1 and where recited in other claims. The working examples describe using only the promoting molecules or the inhibiting molecules, and not both together.

The specification fails to enable the method of claim 15 when using dissociated cells as required bridging lines 5 and 6, producing artificial tissue as in claims 33-36 and combinations as required by claims 37 and 38, and producing a pattern of cells not on a surface as in claims 29 and 31. None of the working examples illustrate these embodiments and it is uncertain how they can be performed. A pattern of cells as produced in the examples is not an artificial tissue. It is uncertain as to how one would use dissociated cells in the place of whole tissue, and the results that would be obtained when using dissociated cells. The examples, describe method steps and results only when applying whole tissue to the prepatterned surface. Cell migration when using whole tissue will not occur when using dissociated cells. None of the working examples show obtaining patterns of cells not on a surface as encompassed by claims 29 and 31. In addition to not being enabling for an artificial tissue, there is no enablement for such tissue being produced not on a surface as in claims 33 and 35.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

112:

5 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph,
10 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and where recited in other claims, "cell-growth promoting molecules and/or cell-growth inhibiting molecules" is
15 confusing since it is unclear how both promoting molecules and inhibiting molecules can be used together. The specification fails to describe how both can be used together to obtain a pattern of cells.

In the last line of claim 1 and where required in other claims, "said cells being whole tissue" is confusing as to when the cells are
20 whole tissue. Does this mean that whole tissue is applied to the surface to form the pattern, or that the patterning produces whole tissue. It is not seen how patterning can produce whole tissue. If whole tissue is placed on the prepatterned surface, then this should be made clear. Additionally, the method should be clear how placing
25 whole tissue on the surface produces a pattern on the surface. Do cells of the whole tissue migrate during culture from the whole

tissue, and during migration follow the pattern on the surface? If this is the case, this should be required by the claims.

Claim 15 is confusing and unclear by reciting in line 3 "in particular according to any of the preceding claims". Claim 15 cannot
5 be optionally dependent on a preceding claim. The claim should be either dependent or not dependent on a preceding claim. If dependent, claim 15 should recite only how the preceding claim is further limited and not repeat what is in a preceding claim. It does not appear claim
10 15 can be dependent on a preceding claim since all preceding claims require the cells to be whole tissue. This precludes "dissociated cells" recited in claim 15 (bridging lines 5 and 6).

In line 2 of claim 19, "comprising" should be --- consisting of -
-- to be a proper and definite Markush group.

Claims 29-36 are confusing and unclear by reciting "producable"
15 since the specification discloses no method other than that of the preceding claim. If not produced by the method of the preceding claim, it is uncertain how the pattern of cells is produced.

Claims 33-36 are confusing by requiring artificial tissue since the steps of method required do not produce artificial tissue.
20 Additionally, it is unclear where the specification discloses steps that produce an artificial tissue. A pattern produced as shown by the examples in the specification is not an artificial tissue.

Claims 37 and 38 are confusing by requiring a combination of patterns and artificial tissues since there is no antecedent basis for
25 steps of a method producing a combination as claimed. A pattern as

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produced by examples in the specification is not a combination as claimed.

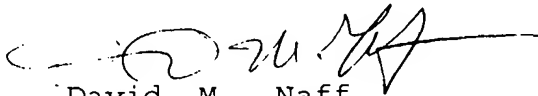
Claims 29, 31, 33 and 35 are unclear by not requiring the pattern or tissue to be on a surface since the method claims require a surface
5 to be present.

The claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be
10 reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

15 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


David M. Naff
Primary Examiner
Art Unit 1651

20 DMN
11/10/03